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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/529,742	07/24/00	RUDIN	V H970M1412US

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EXAMINER

ROSE, S

ART UNIT	PAPER NUMBER
1614	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/529742	Applicant(s) <i>Reed et al</i>
Examiner <i>Skip Ross</i>	Group Art Unit 161

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- Responsive to communication(s) filed on 16/01/2001.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- Claim(s) 18/11 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 18/11 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

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The October 1, 2001 amendment and remarks inform the reader that Rudin et al WO 98/18719 does not correspond to U.S. Patent application 09/297189. However inadvertently the remarks unfortunately fail to inform the reader the 09/297189 is, in fact, now a patent, Rudin et al U.S. 6,254,855 B1, patented July 3, 2001 with 22 claims, including not only claims 1 to 8 to aqueous compositions of "HAP", (hydroxylapatite) particles of overlapped width and length parameters, but also claims 11 and 12, 20 and 21 to toothpastes and chewing gum, and claims 14, 47, to their use in stomatology, (same as herein).

The remarks state that herein, the "HAP" particles have an essential characteristic shape", a "highly anisotropically shaped" HAP particle. However this specification while enabling for ultra finely divided HAP particles fails to disclose to persons skilled in the art how to anisotropically shape them.

The remarks indicate a difference from Rudin '133 (EP 664133-7/25/95-Rudin et al, (Whose HAP particles range in size from 0.015 to 0.06 mm) and are ultra finally divided, by a preamble statement of "stomastic application" herein as compared to bone tissue growth stimulation in Rudin '133. However, the term "stomastic" encompasses "to stimulate reparative osteogenesis processors according to the recital of page 2, line 15, page 3, lines 3-4 "osteoreparative" lines 19-20 page 9, lines 8-9, they stimulate reparative osteogenesis.

Exception is taken to the remarks that the HAP particles are anisotropically shaped HAP particles. A careful re-reading of this specification fails to inform the reader how to anisotropically shape the HAP particles anisotropically shaped" is nowhere mentioned herein.

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The method claims of Rudin et al U.S. 6,254,855, claims 9, 16, 17, and 20 do enable an anisometric especially bar-like shape to HAP particles according to the recitals of page 3, lines 5, 6.

An updated search based on the key words “anisotropically” and “calcium phosphate” (a hydroxyapatite) reveals the following:

Ichitsuka et al (I) U.S. 5,134,009 7/92;

Ichitsuka et al (II) U.S. 5,240,659 8/93;

These describe process for preparing anisotropically shaped HAP particles, but do not anticipate, describe or enablement the product of HAP particles of the claim recited length width and height and provide no guidance on how to makes them.

Applicant is no longer in any tenable position to argue that “anisotropically shaped HAP particles” are “not described in the prior art” but the specification is not enabling on how to make them. Are there any copending application, commonly assigned, that reveal the details on how to make them? Any prior publications on how to make them?

An update search for U.S. patent application 09/297,189 turned up Rudin et al U.S. 6,254,855 with common applicants to Rudin et al herein; it is available for double patenting obviousness-type, even if the Oct. 17, 1997 priority date herein antedates the May 7, 1998 PCT Pub. date of WO 98/18719 and the June 25, 1999 U.S. filing date of Rudin et al.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 to 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to provide enabling guidance on how to make “anisotropically shaped” HAP particles of the claim recited length width and height.

Claims 1 to 11 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon the argument, in remarks, that these HAP particles are “anisotropically shaped” while the specification nowhere even mentions the term “anisotropically shaped”, only “ultra-finely divided” HAP particles, are enabled, being mentioned in the specification, at page 3, line 21, page 5, lines 25 and 26 and in the examples on pages 6, 7 and 8.

Claims 1 to 11 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ultra finely divided HAP particles, does not reasonably provide enablement for anisotropically shaped HAP particles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The explanation has been provided herein above in this office action.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 to 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 8, 11, 12, 14, 17, 20, 21 of U.S. Patent No. 6,254,855 B1. Although the conflicting claims are not patentably distinct from each other because they overlap in scope.

Claims 1 to 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 8, 11, 12, 14, 17, 20, 21 of U.S. Patent No. 6,254,855B1, taken with anyone of each of:

Rubin et al EP 664133 published July 25, 1995 (by applicants herein) who describe these known ultra finely divided hydroxy apatite particles (0.015-0.06 mm).

Sangi LTD, EP 786245, publishes July 30, 1997 who describes these knows ultra finely divided hydroxyapatite particle.

Atsumi et al U.S. 5833959, filed January 23, 1997, patented November 10, 1998, which seems to be the U.S. counterpart of Sangi EP 786245, published July 30, 1997, and additionally in

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view of the dentifrice with hydroxyapatite with particle sizes larger than “ultra finely divided”, (as enabled herein), in each of Scheller (I-II), Bristow et al (I-II-III), Coulson (I-II) and Aoki. These are obvious combinations of ingredients, with no showing of criticality of the particle size claimed.

The statement on page 1, first sentence, “--and curing of caries, peradenitis, and paradentosis--” should be revised by deleting --and curing--, and here there should be added the three paragraphs on the bottom of page 8 and page 9.

The spelling of “chewing gum” should be corrected on page 9, line 6.

Claim 1 to 8, 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rubin et al EP 664133 taken with Atsumi et al U.S. 5833959 (or Sangi EP 786245) and additionally in view of the admitted prior art set forth on page one of the specification.

It was admitted as prior art on page 1 that dentifrices with the excipients of claims 8 and 10 have been described with larger particle sized hydroxyapatite, and there is no showing of criticality of the particle size claimed.

As noted above, claims 1 to 7 differ from Rubin et al EP 664133 (7/25/95) only by a statement of intended use in the preamble of the composition “for stomatic applications” a term that encompasses dentistry other than oral care as set forth on page 9 of the specification, as in this prior art reference.

Claiming an unpatentable old compound, in combination with a carrier, does not render the combination patentable, if it would be obvious to utilize a carrier with a compound. In re Rosicky, 125 USPQ 341; In re Lerner, 169 USPQ 51; Ex parte Douros et al, 163 USPQ 667; and

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In re Craige, 89 USPQ 609; unless the prior art has a negative teaching that the compound was “pharmacologically inert”, In re Wiggins, 158 USPQ 199, Ex parte Frohberger, 168 USPQ 376, or, if use of the specific carrier would not be obvious.

The intended use of an old composition does not render composition claims patentable, in re Zierden, 162 USPQ 102, 104, and the mere preamble statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable, In re Sinex, 135 USPQ 302-305.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday from 7:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*Shep Rose*

Shep Rose  
Senior Primary Examiner  
Art Unit 1614

Rose:mv  
October 25, 2001

SHEP K. ROSE  
PRIMARY EXAMINER  
GROUP 1200